UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JENNIFER BOND, on behalf of herself and all others similarly situated, Plaintiff, v. SANOFI-AVENTIS U.S., LLC; SANOFI US SERVICES INC.; CHATTEM, INC.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; and GLAXOSMITHKLINE LLC, Defendants.	)	**Class Action** **Jury Trial Demanded**

CLASS ACTION COMPLAINT

This is a putative class action on behalf of Plaintiff Jennifer Bond ("Plaintiff") and a Massachusetts Class of all similarly situated individuals against Defendants Sanofi-Aventis U.S. LLC, Sanofi US Services Inc., and Chattem, Inc. (collectively "Sanofi" or "Sanofi Defendants"), Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), and GlaxoSmithKline LLC ("GSK"). Upon the investigation of counsel and, where so alleged, upon information and belief, Plaintiff alleges as follows:

I. NATURE OF THE CASE

1. Plaintiff brings this Massachusetts class action individually and on behalf of the Class defined below of hundreds of thousands of consumers who paid for generic ranitidine products – the generic version of the branded drug Zantac® ("Zantac") –that were unsafe, dangerous, or defective and, when ingested by the human body, yield high quantities of N-Nitrosodimethylamine ("NDMA").

2. Defendants made or marketed branded Zantac. It was reasonably foreseeable, and/or Defendants should have known, that generic equivalents of their Zantac products would perpetuate the same unsafe, dangerous, or defective condition giving rise to NDMA in Defendants' branded Zantac products. Indeed, under the regulatory scheme of the United States Food and Drug Administration ("FDA"), generic ranitidine had to be the same as Defendants' branded Zantac products.

3. Thus, each Defendant owed a duty to Plaintiff and other Class Members to ensure that their own branded Zantac products did not contain any unsafe, dangerous, or defective condition (or disclosed same), which in turn each Defendant should have known would be perpetuated in the generic ranitidine that Plaintiff and other Class Members purchased.

4. Zantac—the brand-name version of the generic drug ranitidine—is used to treat gastrointestinal conditions such as acid indigestion, heartburn, sour stomach, and gastroesophageal reflux disease. The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.

5. Ranitidine was invented by GlaxoSmithKline ("GSK") in the late 1970s and was first sold as Zantac in the United States in 1983.

6. The drug was an immediate blockbuster – shortly after launch, Zantac became the first drug to total $1 billion in sales.[1]

7. In the intervening years since launch as a branded prescription drug, ranitidine has remained one of the most widely prescribed acid reduction medications. Indeed, ranitidine is the

[1] Richard Wright, M.D., How Zantac Became the Best-Selling Drug in History, 16(4) J. HEALTHCARE MARKETING 24 (Winter 1996).

only H-2 receptor antagonist that has been studied specifically for pregnant women and was supposed to be safe for those women, further increasing its market share and perception of safety.[2]

8. However, recent scientific testing of ranitidine has shown that, when ingested and digested by the body, the inherently unstable drug molecule breaks down and produces high quantities of NDMA in the human body. Defendants knew, or should have known, that the chemical reaction would produce NDMA.

9. The World Health Organization's ("WHO") International Agency for Research on Cancer ("IARC") classifies NDMA as one of sixty-six (66) agents that are "probably carcinogenic to humans" (Classification 2A).

10. The U.S. Environmental Protection Agency has likewise classified NDMA as a probable human carcinogen by giving it a "B2" rating, meaning that it is "probably carcinogenic to humans" with little or no human testing data.

11. Indeed, the dangers of NDMA have been well established in the scientific community for many decades.[3]

12. On September 13, 2019, an online pharmacy named Valisure LLC and ValisureRX LLC (collectively "Valisure") submitted a citizen's petition which stated that it

[2] Larson JD, et al., "Double-blind placebo-controlled study of ranitidine for gastroesophageal reflux symptoms during pregnancy." Obstet Gynecol 1997; 90:83-7.

[3] Even as far back as the 1970s, studies were being conducted about NDMA, and their potential contamination of foodstuffs. https://www.who.int/ipcs/publications/cicad/en/cicad38.pdf For example, Canada showed such concern about the potential ingestion of NDMA that they amended regulations as far back as 1975, permissible levels of nitrite in cured meat products were lowered and the use of nitrate was eliminated, except for a few classes of products (including "slowcured" meats) (G. Lawrence, personal communication, 1999). *Id.*

tested ranitidine and it "detected extremely high levels of NDMA in all lots [of ranitidine] tested, across multiple manufacturers of ranitidine products."[4]

13. The testing protocol utilized by Valisure, employing the same methodologies used by regulatory agencies, including the FDA, detected 2,511,469 nanograms ("ng") of NDMA per 150 milligrams ("mg") tablet of ranitidine.[5]

14. Valisure subsequently conducted additional GC/MS testing at body temperature to analyze Zantac in simulated gastric fluid. When researchers placed 1 150 mg tablet into 100 mL of simulated gastric fluid, they still found up to 300,000 ng of NDMA.[6]

15. The FDA recently announced an interim permissible intake limit of 96 ng of NDMA per day.[7] As such, a single dose of ranitidine results in exposure to NDMA that is roughly 26,000 times greater than the FDA's daily intake limits.

16. These levels are consistent with scientific literature, reporting on testing which has found dangerous levels of NDMA in the urine of those who have taken ranitidine.[8] Specifically, an article by Zeng and Mitch showed that a single 150 mg pill of Zantac resulted in the human body being exposed to approximately 4 million ng of NDMA.[9]

17. Defendants knew, should have known, or were deliberately indifferent to this testing during the times when each sold or marketed branded Zantac products.

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[4] Valisure Citizen Petition to FDA ("Citizen Petition") at 6 (emphasis added), available at https://hbw.pharmaintelligence.informa.com/~/media/Supporting%20Documents/Rose%20Sheet/2019/09/9%20Sept%202019%20Valisure%20Ranitidine%20Petition.pdf.

[5] *Id.*

[6] Peter Attia, The Drive, Episode #75: "David Light: Zantac recall due to cancer concerns – what you need to know," *available at* https://peterattiamd.com/davidlight/, at 1:15-1:20.

[7] FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan), FDA (last updated Aug. 28, 2019) (setting "interim limits for NDMA" and other nitrosamines at 96 ng/day for angiotensin II receptor blockers).

[8] Teng Zeng & William A. Mitch, Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine, 37(6) Carcinogenesis 625 (Mar. 18, 2016).

[9] *See also* Peter Attia, The Drive, Episode #75: "David Light: Zantac recall due to cancer concerns – what you need to know," *available at* https://peterattiamd.com/davidlight/, at 1:00-1:03.

18. At all relevant times, Defendants had a duty to ensure that their branded Zantac drug products were safe and did not contain undisclosed risks or flaws, including exposing consumers to any risk of carcinogenic contamination.

19. Defendants knew, or should have known, or were deliberately reckless, that any deficiencies in the labeling, manufacturing, or design for their branded Zantac drug products would foreseeably be perpetuated for any generic ranitidine products that were required to be the "same" as Defendants' branded Zantac products.

20. Each Defendant had an ongoing duty to update their branded Zantac labeling to adequately disclose the risk of NDMA. FDA regulations explicitly provide that each Defendant, as a holder of a New Drug Application ("NDA"), could have supplemented or updated their Zantac labeling without prior FDA approval. These changes, in turn, would necessarily have triggered label changes for generic manufacturers. However, because no Defendant ever adequately discharged its duty to disclose information about NDMA or to design away the problem inherent in the drug's molecular structure, neither did generic ranitidine manufacturers. This resulted in Plaintiff and other Class Members purchasing dangerous, unsafe, and essentially worthless generic ranitidine products.

21. Zantac was marketed in prescription and over-the-counter forms. GSK first obtained FDA approval to sell prescription Zantac in 1983. Pfizer obtained FDA approval to sell over-the-counter Zantac in 2004.

22. Beginning in 1994, several companies initially sought and received FDA approval to sell prescription generic ranitidine that was bioequivalent to GSK's prescription Zantac. GSK continued to sell prescription Zantac for many years despite prescription generic and OTC entry

into the market. Indeed, GSK did not stop selling prescription Zantac until mid-2017 or mid-2018.

23. Throughout the time GSK sold prescription Zantac, each generic manufacturer's prescription ranitidine product and labeling had to be the same as GSK's branded product and labeling. For instance, generic drug manufacturers have an ongoing federal duty of sameness in their products. Under 21 U.S.C. § 355(j), the generic manufacturer must show the following things as relevant to this case: the active ingredient(s) are the same as the RLD, § 355(j)(2)(A)(ii); and, that the generic drug is "bioequivalent" to the RLD and "can be expected to have the same therapeutic effect," id. at (A)(iv). A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA. Id. at (A)(vi); see also § 355(b)(1)(C).

24. A generic manufacturer must also submit information to show that the "labeling proposed for the new drug is the same as the labeling approved for the [RLD][.]" 21 U.S.C. § 355(j)(2)(A)(v).

25. In short, each manufacturer of generic prescription ranitidine had to ensure its product and associated labeling was the same as GSK's prescription Zantac products. Unfortunately for Plaintiff and other Class Members, this foreseeably resulted in the same flaw that led to NDMA arising in GSK's Zantac products to arise in generic manufacturer's generic prescription ranitidine products. In turn, Plaintiff and other Class Members purchased unsafe, dangerous, defective, and essentially worthless generic ranitidine that exposed them to an undisclosed risk of NDMA.

26. As with prescription Zantac, generic manufacturers in or around 1994 eventually sought and received FDA approval to sell generic over-the-counter ranitidine versions of over-the-counter Zantac.

27. As with the regulatory regime for generic prescription drugs, generic over-the-counter drugs also must be the same, in terms of composition and labeling, as the branded products being emulated. For instance, both types of generic drugs must demonstrate and indicate on their labels that they have the same active ingredient, indication, route of administration and safety and efficacy labelling as their branded counterparts. See 21 C.F.R. § 201.66; 21 U.S.C. § 355(j)(2)(A).

28. GSK sold the rights to over-the-counter Zantac to Boehringer or about October 2006, at which time Boehringer began manufacturing and distributing the product. Also starting at this time, until approximately January 2017, Boehringer also assumed a duty and regulatory responsibility to ensure that over-the-counter Zantac was not unsafe, dangerous, or defective; specifically, that it did not yield NDMA, or at least to disclose the risk of NDMA. Because of Boehringer's reckless disregard for its duty, generic over-the-counter ranitidine carried the same undisclosed NDMA risk as Boehringer's over-the-counter branded Zantac product.

29. In or about January 2017, Sanofi acquired the rights to over-the-counter Zantac and has manufactured and distributed the drug during that period. Upon the acquisition of these rights in January of 2017, Sanofi assumed a duty and regulatory responsibility to ensure that over-the-counter Zantac was not unsafe, dangerous, or defective; specifically, that it did not yield NDMA, or at least to disclose the risk of NDMA. Because of Sanofi's reckless disregard for its duty, generic over-the-counter ranitidine carried the same undisclosed NDMA risk as Sanofi's over-the-counter branded Zantac product.

II. JURISDICTION AND VENUE

30. This Court has original jurisdiction pursuant to the Class Action Fairness Act, 28 U.S.C. § 1332(d), because (a) at least one member of the proposed Class is a citizen of a state different from that of Defendants, (b) the amount in controversy exceeds $5,000,000, exclusive of interest and costs, (c) the proposed Class consists of more than 100 Class Members, and (d) none of the exceptions under the subsection apply to this action.

31. This Court has personal jurisdiction over Defendants because each Defendant has sufficient minimum contacts in Massachusetts, and otherwise intentionally avails itself of the markets within Massachusetts through its business activities, such that the exercise of jurisdiction by this Court is proper and necessary.

32. Venue is proper in this Court pursuant to 28 U.S.C. § 1391, because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in this District, a substantial part of the property that is the subject of this action is situated in this District, and the Defendants are subject to personal jurisdiction in this District.

III. PARTIES

33. Plaintiff Jennifer Bond is a resident of Middlesex County, residing in Chelmsford, Massachusetts. During the Class period, Plaintiff paid money for one or more generic ranitidine products. Had Defendants' deception about the risks associated with their branded Zantac products been made known earlier, it is unlikely that an Abbreviated New Drug Application ("ANDA") or similar regulatory clearance would have been given to a generic manufacturer, and/or any generic ranitidine products approved would have had additional warnings or discussion of NDMA contamination. But for Defendants' conduct, Plaintiff would not have paid for generic versions of ranitidine.

34. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi.

35. Defendant Sanofi US Services Inc. is a Delaware corporation with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807, and is a wholly owned subsidiary of the French company Sanofi.

36. Defendant Chattem, Inc. is a Tennessee corporation with a principal place of business at 1715 West 38th Street Chattanooga, Tennessee 37409, and is a wholly owned subsidiary of the French company Sanofi.

37. Sanofi Defendants controlled the U.S. rights to Zantac from about January 2017 to the present and manufactured and distributed the drug in the United States during that period.

38. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877, and is a subsidiary of the German company Boehringer Ingelheim Corporation. Boehringer owned the U.S. rights to over-the-counter Zantac from about October 2006 to January 2017 and manufactured and distributed the drug in the United States during that period.

39. Defendant GSK is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at the Philadelphia Navy Yard, 5 Crescent Drive, Philadelphia, Pennsylvania 19112. GSK is a wholly-owned subsidiary of GlaxoSmithKline PLC, a British public limited company that is registered to do business in the United States. GSK first applied for, and received, approval for prescription Brand Zantac, the application for which was the RLD for generic ranitidine for some or all of the relevant time period.

IV. FACTUAL ALLEGATIONS

A. The Brand and Generic Drug Approval Framework

40. The Drug Price Competition and Patent Term Restoration Act of 1984 – more commonly referred to as the Hatch-Waxman Act – is codified at 21 U.S.C. § 355(j).

41. Brand drug companies submitting an NDA are required to demonstrate clinical safety and efficacy through well-designed clinical trials. 21 U.S.C. § 355 et seq.

42. Manufacturers of an approved drug are required by regulation to submit an annual report to the FDA containing, among other things, new information regarding the drug's safety.

43. The report is required to contain "[a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product. The report is also required to contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit a labeling supplement, add a warning to the labeling, or initiate a new study."[10]

44. The manufacturer's annual report also must contain "[c]opies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (e.g., mutageniticity) conducted by, or otherwise obtained by, the [manufacturer] concerning the ingredients in the drug product.[11]

45. By contrast, generic drug companies submit an ANDA. Instead of demonstrating clinical safety and efficacy, generic drug companies need only demonstrate bioequivalence to the brand or reference listed drug.

46. This is true whether a generic drug company seeks to sell a generic version of a prescription drug or an over-the-counter drug. See 21 U.S.C. § 355(j) et seq.

[10] 21 C.F.R. § 314.81(b)(2).
[11] 21 C.F.R. § 314.81(b)(2)(v).

47. In addition, brand drug manufacturers may unilaterally supplement or update their drug's labeling under the FDA's "changes being effected" or "CBE" regulations. FDA regulations permit manufacturers to use the Changes Being Effected ("CBE") process to "add or strengthen a contraindication, warning, precaution, or adverse reaction . . .," 21 C.F.R. § 314.70(c)(6)(iii)(A), as well as to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," 21 C.F.R. § 314.70(c)(6)(iii)(C), without prior FDA approval.

B. Background: Zantac and Ranitidine

48. Zantac was developed by GSK and approved for prescription use by the FDA in 1983. Generic competition entered the market in 1994.

49. The drug belongs to a class of medications called histamine H2-receptor antagonists (or H2 blockers), which decrease the amount of acid produced by the stomach and are used to treat gastric ulcers, heartburn, acid indigestion, sour stomach, and other gastrointestinal conditions.[12]

50. Zantac became available without a prescription in 2004.

C. Weaknesses in GSK's Safety Studies of Zantac

51. In conjunction with their application to the FDA, GSK was required to conduct and submit safety studies of Zantac to ensure that there were no unnecessarily high risks associated with the drug.

52. The safety studies conducted by GSK contained important weaknesses in the studies' investigations.

[12] Histamine H2 Antagonist (Oral Route, Injection Route, Intravenous Route), MAYO CLINIC (last updated October 5, 2019), https://www.mayoclinic.org/drugs-supplements/histamine-h2- antagonist-oral-route-injection-route-intravenous-route/description/drg-20068584.

53. In a 1981 study published by GSK, the metabolites of ranitidine in urine were studied using industry standard detection technology of high-performance liquid chromatography.[13]

54. The study investigated many potential metabolites, and listed those metabolites which were studied, but there is no indication that NDMA was looked for in the results despite the fact that it is entirely predictable that ranitidine (which contains both a nitrite and dimethylamine) would combine to form NDMA.

55. By 1987, after numerous studies raised concerns over ranitidine and cancerous nitroso compounds, GSK published a clinical study specifically investigating gastric contents in human patients and N-nitroso compounds.[14]

56. The study concluded that, "[d]uring treatment with ranitidine median 24 hour intragastric pH, nitrate concentration, and counts of total and nitrate reducing bacteria increased significantly regardless of dietary nitrate content; there was no significant increase in the median day time concentration of N-nitroso compounds."

57. This study, which was funded and published by Defendant GSK, and conducted in response to other scientific studies questioning the association,[15] had the effect of building confidence in the medical community that ranitidine was not associated with NDMA. GSK has a

[13] Carey, P.F., Martin, L.E., Owen, P.E. (1981). Determination of ranitidine and its metabolites in human urine by reversed-phase ion-pair high-performance liquid chromatography. Journal of Chromatography B: Biomedical Sciences and Applications. Vol. 225, 1, p. 161-168 (https://www.sciencedirect.com/science/article/pii/S0378434700802558).

[14] Thomas, J.M., et al. (1987). Effects of one year's treatment with ranitidine and of truncal vagotomy on gastric contents. Gut. Vol. 28, 6, p. 726-738 (https://www.ncbi.nlm.nih.gov/pubmed/3623220)

[15] Maura, A. et al. (1983) DNA damage induced by nitrosated ranitidine in cultured mammalian cells. Toxicology Letters. Vol. 18, 1-2, p. 97-102 (https://www.sciencedirect.com/science/article/pii/0378427483900772).

long and well-documented history of polluting the medical literature with ghost-written studies favorable to GSK's products.[16]

58. This study's GSK-favorable outcome was no exception, and yet it contained many serious flaws.

59. First, this study used an analytical system called a "nitrogen oxide assay" for the determination of N-nitrosamines, which was developed for analysis of food and is a detection method that indirectly and non-specifically measures N-nitrosamines. A more accurate means to test for NDMA would have been to have conducted an industry standard chromatographic analysis.

60. In addition to being a less accurate and less specific detection method than industry standard chromatography, this method necessitated discarding all gastric samples that contained ranitidine.

D. Instability of the Ranitidine Molecule in Human Conditions

61. Acid drugs generally, such as Zantac/ranitidine, are known to increase stomach pH and thereby increase the growth of nitrate-reducing bacteria. This combination results in further elevated levels of nitrates.

62. The reduction of nitrate-reducing bacteria as a result of acid reducers is a well known phenomenon and was specifically studied with ranitidine in the original approval of the drug.[17]

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[16] *See, e.g.*, "…GlaxoSmithKline….often paid ghostwriters to pen medical studies, editorials and even a textbook that listed physicians as the authors…" https://www.propublica.org/article/drug-company-used-ghostwriters-to-write-work-bylined-by-academics-documents; "…The Advair marketing campaign also utilized GSK employees to ghostwrite medical journal articles in a way that that implied that Advair was safe and effective for all asthma disease states, including mild asthma" Unsealed Whistleblower complaint at https://www.kenneymccafferty.com/pdf/GSK/02.03.12%20-%20GSK%20--%207th%20Amended%20Complaint.pdf

[17] Frank, LLP provided Valisure with hard copies of Glaxo and FDA documents concerning NDA 18-703 from the FDA that it obtained pursuant to the Freedom of Information Act, 5 U.S.C. § 552 *et seq*.

63. Indeed, NDMA formation in the stomach has been a concern for many years and specifically ranitidine has been implicated as a cause of NDMA formation by multiple research groups including those at Stanford University.[18]

64. Beyond just the possibility of the stomach's ability to create NDMA, Valisure identified a possible enzymatic mechanism via dimethylarginine dimethylaminohydrolase ("DDAH") for the liberation of ranitidine's DMA group which can occur in other tissues and organs separate from the stomach.

65. Liberated DMA can lead to the formation of NDMA when exposed to the nitrites present on the ranitidine molecule, nitrites freely circulating in the body,[19] or other potential pathways particularly in weak acidic conditions[20] such as that in the kidney or bladder.

66. Indeed, scientific literature dating back as far as 1989 details the discovery of the DDAH enzyme and specifically comments on the propensity of DMA to form NDMA.[21]

E. In Vivo Studies Since the Launch of Brand Zantac Strongly Suggested Ranitidine's Formation of NDMA and Carciogenicity

67. Only two years after GSK launched branded prescription Zantac, a study published in the journal Carcinogenesis in 1983 titled "Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite" specifically suspected the carcinogenic nature of ranitidine in combination with nitrite.[22]

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[18] Zeng, T. and Mitch, W.A. (2016). Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine. Carcinogenesis. Vol. 37, p. 625-634 (https://www.ncbi.nlm.nih.gov/pubmed/26992900).
12 Rassaf, T., Ferdinandy, P., and Schulz, R. (2013). Nitrite in organ protection. British Journal of Pharmacology. Vol. 171, 1, p. 1-11 (https://bpspubs.onlinelibrary.wiley.com/doi/full/10.1111/bph.12291).
[19] Rassaf, T., Ferdinandy, P., and Schulz, R. (2013). Nitrite in organ protection. British Journal of Pharmacology. Vol. 171, 1, p. 1-11 (https://bpspubs.onlinelibrary.wiley.com/doi/full/10.1111/bph.12291).
[20] Showing metabocard for Dimethylamine. ID HMDB0000087. The Human Metabolome Database. (http://www.hmdb.ca/metabolites/HMDB0000087)
[21] Ogawa, T., Kimoto, M., and Sasaoka, K. (1989). Purification and properties of a new enzyme, NG, NG-dimethylarginine dimethylaminohydrolase, from rat kidney. The Journal of Biological Chemistry. Vol. 264, No. 17 p. 10205-10209 (http://www.jbc.org/content/264/17/10205.full.pdf)
[22] Brambilla, G. et al. (1983). Genotoxic effects in rodents given high oral doses of ranitidine and sodium nitrite. Carcinogenesis. Vol. 4, 10, p. 1281-1285 (https://academic.oup.com/carcin/article-abstract/4/10/1281/2391364)

68. Beyond that animal study, there have also been numerous in vivo studies conducted with humans and ranitidine.

69. One such study was completed and published in 2016 by Professor William Mitch and his team at Stanford University and showed that healthy individuals, both male and female, that took Zantac 150 mg tablets produced roughly 400 times more NDMA in their urine (over 40,000 ng) in the resulting 24 hours after ingestion.[23]

70. NDMA has been implicated as an etiological agent for bladder cancer, however, the implications could be significantly worse given that NDMA is known to be heavily absorbed by the body instead of being excreted into urine.[24]

F. Valisure's Citizen Petition

71. Valisure is an "online pharmacy currently licensed in 38 states and an analytical laboratory that is ISO 17025 accredited by the International Organization for Standardization." Valisure also is registered with the Drug Enforcement Administration and the FDA.

72. On September 13, 2019, Valisure conducted its own independent testing of ranitidine using the FDA's own gas chromatography/mass spectrometry ("GC/MS") protocol.

73. The tests conducted by Valisure show that "ranitidine can react with itself in standard analysis conditions . . . at high efficiency to produce NDMA at dangerous levels well in excess of the permissible daily intake limit for this probable carcinogen."

74. The testing protocol utilized by Valisure, employing the same methodologies used by all regulatory agencies, including the FDA, detected 2,511,469 ng of NDMA per 150 mg tablet of ranitidine.[25]

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[23] Zeng, T. and Mitch, W.A. (2016). Oral intake of ranitidine increases urinary excretion of N-nitrosodimethylamine. Carcinogenesis. Vol. 37, p. 625-634 (https://www.ncbi.nlm.nih.gov/pubmed/26992900).

[24] Spiegelhalder, B., Eisenbrand, G., Preussmann, R. (1982). Urinary excretion of N-nitrosamines in rats and humans. IARC Sci Publ. Vol. 41 p. 443-449 (https://www.ncbi.nlm.nih.gov/pubmed/7141551).

75. According to Valisure, after investigating the information available to it regarding the safety studies submitted by GSK, Valisure found them to be insufficient to rule out potential carcinogenic properties.[26]

76. Valisure also found a weakness in the testing methodology that likely enabled the specific issue of the possibility of ranitidine producing these astronomically high levels of carcinogen upon ingestion to go undetected.[27]

G. Regulatory and Industry Recalls

77. As a result of the news, regulatory agencies around the world have leapt to recall the drug.

78. On September 17, 2019, Health Canada, the department of the Canadian government responsible for national public health stated, "companies marketing ranitidine products in Canada have stopped any further distribution until evidence is provided to demonstrate that they do not contain NDMA above acceptable levels.[28]

79. Other regulatory agencies around the world have followed suit, including Germany, Switzerland, Austria, Finland, Singapore, and Qatar.

80. Chain pharmacies have likewise begun discontinuing the drug, including Walmart, CVS and Walgreens.

H. Manufacturer Recalls

[25] *Id.*
[26] Citizen Petition at 13.
[27] *Id.*
[28] Information Update – Health Canada requests that companies stop distributing ranitidine drugs in Canada while it assesses NDMA; some products being recalled, CISION CANADA (Sept. 25, 2019),https://www.newswire.ca/news-releases/information-update-health-canada-requests-that-companies-stop-distributing-ranitidine-drugs-in-canada-while-it-assesses-ndma-additional-products-being-recalled-847192947.html.

81. On September 13, 2019, Sandoz, Inc. became the first United States manufacturer of ranitidine to begin recalling the product. The company recalled all unexpired ranitidine and announced it would notify all distributors and customers of its action.[29]

82. Subsequently on October 1, 2019, Dr. Reddy's Laboratories, as well as its subsidiaries, announced a nationwide recall of its ranitidine products. This recall was subsequently posted by the FDA on October 23, 2019. This recall includes Walgreens's and CVS's generic versions of ranitidine, among others.[30]

83. On October 18, 2019, Sanofi initiated a recall of all Zantac over-the-counter product in the United States.[31]

84. On October 25, 2019, Novitium Pharma also announced a recall of all its unexpired ranitidine products.[32]

85. As of the date of this filing, there are still manufacturers who continue to sell ranitidine product within the United States.

I. Fraudulent Concealment and Tolling

86. Plaintiff's and Class Members' causes of action first accrued on the date of the Valisure Citizen's Petition to the FDA.

87. Alternatively, any statute of limitation or prescriptive period is equitably tolled by Defendants' fraudulent concealment. Defendants each affirmatively concealed from Plaintiff and other Class Members their unlawful conduct. Each Defendant affirmatively to avoided disclosing the known risks associated with Zantac.

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[29] FDA, (Sept. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-voluntary-recall-ranitidine-hydrochloride-capsules-150mg-and-300mg-due-elevated.
[30] FDA, (Oct. 23, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/dr-reddys-confirms-its-voluntary-nationwide-recall-all-ranitidine-products-us-market.
[31] FDA, (Oct. 22, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sanofi-provides-update-precautionary-voluntary-recall-zantac-otc-us.
[32] FDA, (Oct. 25, 2019), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/novitium-pharma-issues-voluntary-national-recall-ranitidine-hydrochloride-capsules-150mg-and-300mg.

88. For instance, GSK actively conducted a flawed and deliberately misleading and reckless investigation in response to unfavorable medical studies to quiet any concerns regarding their Zantac product and its capacity to create NDMA in the human body.

89. Furthermore, each Defendant continued to represent and warrant that their brand Zantac products were safe and intentionally did not disclose the risk posed by NDMA.

90. Because of this, Plaintiff and other Class Members did not discover, nor would they discover through reasonable and ordinary diligence, each Defendant's reckless, deceptive, fraudulent, and unlawful conduct alleged herein. Defendants' false and misleading explanations, or obfuscations, lulled Plaintiff and Class Members into believing that Zantac, and consequently generic ranitidine, were safe despite their exercise of reasonable and ordinary diligence.

91. As a result of each Defendant's affirmative and other acts of concealment, any applicable statute of limitations affecting the rights of Plaintiff and other Class Members has been tolled. Plaintiff and/or other Class Members exercised reasonable diligence by among other things promptly investigating and bringing the allegations contained herein. Despite these or other efforts, Plaintiff was unable to discover, and could not have discovered, the unlawful conduct alleged herein at the time it occurred or at an earlier time to enable this complaint to be filed sooner.

J. Plaintiff's Factual Allegations

92. Plaintiff Jennifer Bond is a Massachusetts resident. For many years, Plaintiff has purchased generic ranitidine.

93. The generic ranitidine Plaintiff purchased was unsafe, dangerous, or defective, and essentially worthless, due to the undisclosed risk of NDMA flowing from Defendants' reckless failures to adequately discharge their duties to disclose such risk for their branded

Zantac products, or remove them from the market, which foreseeably would have been perpetuated by the manufacturers of the generic ranitidine.

V. CLASS ACTION ALLEGATIONS

94. Plaintiff brings this action both individually and as a class action pursuant to Fed. R. Civ. P. 23(a), 23(b)(1), 23(b)(2), 23(b)(3), and 23(c)(4) against Defendants on their own behalf and on behalf of a Class defined below:

> All individuals in the Commonwealth of Massachusetts who, within the applicable limitations period, paid any amount of money out of pocket (for personal or household use) for generic ranitidine.

95. Plaintiff further pleads alternative Sub-Class[es] under Rule 23(c)(4) for any issue the Court may deem appropriate, or warranted by further discovery.

96. Excluded from the Class and Sub-Class[es] are: (a) any Judge or Magistrate presiding over this action, and members of their families; (b) Defendants and affiliated entities, and their employees, officers, directors, and agents; (c) Defendants' legal representatives, assigns and successors; and (d) all persons who properly execute and file a timely request for exclusion from any Court-approved class.

97. Plaintiff reserves the right to narrow or expand the foregoing class definition, or to create further sub-classes as the Court deems necessary.

98. Plaintiff meets the prerequisites of Rule 23(a) to bring this action on behalf of the Class and Sub-Class[es].

99. **Numerosity:** While the exact number of Class Members cannot be determined without discovery, they are believed to consist of potentially millions of ranitidine consumers nationwide. Indeed, in 2018 global sales of over-the-counter Zantac totaled approximately $142

million, up over 14% year over year.[33] The Class Members are therefore so numerous that joinder of all members is impracticable.

100. **Commonality:** Common questions of law and fact exist as to all Class Members, including but not limited to:

a. Whether each Defendant had and breached any duty to ensure their respective branded Zantac products were not unsafe, dangerous, or defective;

b. Whether each Defendant had a duty to warn about any NDMA risk;

c. Whether generic manufacturers' ranitidine products purchased by Plaintiff and other Class Members had to be the same as Defendants' branded Zantac products, and carried the same undisclosed NDMA risk;

d. Whether it was foreseeable that Defendants' wrongful conduct vis-à-vis NDMA risk would be perpetuated by generic manufacturers of generic ranitidine;

e. Whether each Defendant recklessly misrepresented or omitted facts about its brand Zantac;

f. Whether each Defendant recklessly misrepresented or omitted facts regarding the safety of its brand Zantac;

g. Whether Plaintiff and other Class Members have been injured as a result of each Defendant's unlawful conduct, and the amount of damages;

h. Whether a common damages model can calculate damages on a classwide basis;

i. When Plaintiff'' and Class Members' causes of action have accrued;

j. Whether Defendants fraudulently concealed Plaintiff's and Class Members' causes of action.

[33] Redman, Russell, (Oct. 18, 2019) Over-the-counter Zantac recalled in U.S. and Canada, Supermarket News, https://www.supermarketnews.com/health-wellness/over-counter-zantac-recalled-us-and-canada.

101. **Typicality:** Plaintiff's claims are typical of Class Members' claims. Plaintiff and Class Members all suffered the same type of economic harm. Plaintiff have substantially the same interest in this matter as all other Class Members, and their claims arise out of the same set of facts and conduct as all other Class Members.

102. **Adequacy of Representation:** Plaintiff is committed to pursuing this action and have retained competent counsel experienced in pharmaceutical litigation, consumer fraud litigation, class action, and federal court litigation. Accordingly, Plaintiff and her counsel will fairly and adequately protect the interests of Class Members. Plaintiff's claims are coincident with, and not antagonistic to, those of the other Class Members they seek to represent. Plaintiff has no disabling conflicts with Class Members and will fairly and adequately represent the interests of Class Members.

103. The elements of Rule 23(b)(2) are met. Defendants have acted on grounds that apply generally to Class Members so that preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate as to the Class as a whole.

104. The elements of Rule 23(b)(3) are met. Here, the common questions of law and fact enumerated above predominate over the questions affecting only individual Class Members, and a class action is the superior method for fair and efficient adjudication of the controversy. Although many other Class Members have claims against Defendants, the likelihood that individual Class Members will prosecute separate actions is remote due to the time and expense necessary to conduct such litigation. Serial adjudication in numerous venues is furthermore not efficient, timely or proper. Judicial resources will be unnecessarily depleted by resolution of individual claims. Joinder on an individual basis of thousands of claimants in one suit would be impractical or impossible. In addition, individualized rulings and judgments could result in

inconsistent relief for similarly situated Plaintiffs. Plaintiff's counsel, highly experienced in class actions and federal court litigation, foresee little difficulty in the management of this case as a class action.

CLAIMS FOR RELIEF

COUNT I – RECKLESSNESS

105. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

106. Plaintiff purchased products that were the generic bioequivalents of Defendants' branded Zantac drug products.

107. At all relevant times, Defendants had a duty to ensure that their branded Zantac drug products were safe and did not contain undisclosed risks or flaws, including exposing consumers to any risk of carcinogenic contamination.

108. Defendants knew, or should have known, or were deliberately indifferent, that any deficiencies in the labeling, manufacturing, or design for their branded Zantac drug products would foreseeably be perpetuated for any generic bioequivalents.

109. Defendants owed Plaintiff and other Class Members, and/or their prescribing physicians, duties to exercise reasonable or ordinary care and/or not to be recklessly indifferent under the circumstances in light of the generally recognized and prevailing scientific knowledge to ensure that their branded Zantac drug products were properly manufactured, designed, and accompanied by adequate warnings at all times, all of which in turn would foreseeably be perpetuated by generic bioequivalents.

110. Through the conduct described in this Complaint, Defendants breached their duties to Plaintiff and other Class Members, and/or to Plaintiff's physicians.

111. Defendants knew, or should have known, or were deliberately indifferent that, due to their failure to use reasonable care or their reckless indifference, Plaintiff and other Class Members, and/or Plaintiff's physicians, would use and did use generic bioequivalent products of Defendants' branded Zantac products.

112. As a legal and proximate result of Defendants' recklessness, Plaintiff sustained the injuries and damages set forth herein.

113. Defendants' conduct was wanton and reckless, the circumstances for which justify punitive damages to deter such future conduct.

COUNT II – RECKLESS MISREPRESENTATION/OMISSION

114. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

115. At all relevant times, Defendants were engaged in the business of manufacturing, marketing, distributing, and selling branded Zantac products.

116. At all relevant times, Defendants had a duty to ensure that their branded Zantac drug products were safe and did not contain undisclosed risks or flaws, including exposing consumers to any risk of carcinogenic contamination.

117. Defendants knew, or should have known, or were deliberately indifferent, that any deficiencies in the labeling, manufacturing, or design for their branded Zantac drug products would foreseeably be perpetuated for any generic bioequivalents.

118. In the course of manufacturing, designing, labeling, and marketing branded Zantac products, Defendants knew, or should have known, or were deliberately indifferent, that they made untrue or misleading representations of material fact and/or omitted material information about the manufacture, design, safety, contents, and risks relating to their brand

Zantac drug products, all of which Defendants know, or should have known, or were recklessly indifferent to whether, would be perpetuated for any generic bioequivalents.

119. Plaintiff purchased products that were the generic bioequivalents of Defendants' branded Zantac drug products.

120. To the extent applicable, Plaintiff and other Class Members reasonably relied on such misrepresentations and/or omissions and were thereby induced to purchase generic bioequivalents of Defendants' branded Zantac products.

121. Plaintiff and other Class Members would not have purchased or used these products had they known of the true safety risks or flaws, including the exposure to carcinogenic contamination.

122. Defendants were reckless in making these untrue misrepresentations and/or omitting material information because Defendants know, or had reason to know, or were deliberately indifferent, of the actual, unreasonable dangers and defects in their products, which in turn would foreseeably be perpetuated for generic bioequivalents.

123. Plaintiff and other Class Members were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to Defendants' branded Zantac drug products, which in turn would foreseeably be perpetuated for generic bioequivalents.

124. As a legal and proximate result of Defendants' reckless misrepresentations and/or omissions, Plaintiff and other Class Members sustained the injuries and damages set forth herein.

125. Defendants' conduct was wanton and reckless, the circumstances for which justify punitive damages to deter such future conduct.

COUNT III – FRAUDULENT CONCEALMENT

126. Plaintiff incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

127. At all relevant times, Defendants were engaged in the business of manufacturing, marketing, distributing, and selling branded Zantac products.

128. At all relevant times, Defendants held out their branded Zantac products as being safe and not posing any risk of carcinogenic contamination.

129. Defendants intentionally concealed that their brand Zantac drug products were unsafe or defective due to carcinogenic contamination.

130. Defendants affirmatively misrepresented in their regulatory submissions, and labeling, that their branded Zantac drug products were safe, not defective, and did not expose consumers to any risk of carcinogenic contamination.

131. Defendants knew or were deliberately indifferent of the defect and risk in their branded Zantac drug products when they made the foregoing misrepresentations.

132. Defendants knew, or should have known, or were deliberately indifferent, that any deficiencies in the labeling, manufacturing, or design for their branded Zantac drug products would foreseeably be perpetuated for any generic bioequivalents.

133. Plaintiff and other Class Members did not know, and could not through ordinary diligence discover, that Defendants' branded Zantac drug products were not safe and exposed consumers to a risk of carcinogenic contamination, all of which were foreseeably perpetuated by generic bioequivalents. In turn, Plaintiff and other Class Members did not know, and could not

through ordinary diligence discover, that generic bioequivalents of Defendants' branded Zantac drug products were not safe and exposed consumers to a risk of carcinogenic contamination.

134. Defendants had a duty to disclose that their branded Zantac products are flawed as alleged herein, and that the flaw or defect created a foreseeable risk to Plaintiff and other Class Members who purchased generic bioequivalents of Defendants' branded Zantac drug products.

135. Defendants' misrepresentations or omissions where material to consumers because they related to safety and risks for branded Zantac drug products, which in turn would foreseeably be perpetuated for generic bioequivalents.

136. As a legal and proximate result of Defendants' fraudulent concealment, Plaintiff and other Class Members sustained the injuries and damages set forth herein.

137. Defendants' conduct was wanton and reckless, the circumstances for which justify punitive damages to deter such future conduct.

COUNT IV – MEDICAL MONITORING

138. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows:

139. As a proximate result of Defendants' acts and omissions, Plaintiff and other Class Members are at an increased risk of developing cancer above the normal base-level risk.

140. As alleged above, each Defendant's Zantac product yielded NDMA, an agent known to cause cancer in humans. Defendants' failure to disclose this led to the foreseeable result that each generic manufacturer's generic ranitidine product yielded NDMA as well.

141. Plaintiff and other Class Members may not develop cancer for many years.

142. Plaintiff and other Class Members are at an increased risk as they consumed and/or ingested generic ranitidine for extended periods of time, some as many as several years, and as a result were exposed to a contaminant.

143. Upon information and belief and based upon the internal and external investigations now made public, Plaintiff and other Class Members are at an increased risk as they were exposed to NDMA.

144. NDMA is a hazardous, life-threatening, toxic substance that is known to cause cancer in humans.

145. Plaintiff and other Class Members are at an increased risk of cancer as they were exposed to, consumed, and/or ingested generic ranitidine in quantities, and over periods of time sufficient to establish an exposure level that is considered to be hazardous to health, and that is considered to be sufficient to cause cancer or increase the risk of developing cancer.

146. The FDA's choice of 96 ng per day of NDMA as the safe threshold equates to 35,040 ng per year. A person who takes a single 150 mg tablet of Zantac may be exposed to as much as 4 million ng of NDMA, more than 114 times over the FDA consumption threshold for an entire year. Thus, Plaintiff's and other Class Members' increased risk is both frightening and significant.[34]

147. The exposure was caused solely and proximately by Defendants' failure to adequately manufacture, design, and label their branded Zantac products, all of which in turn would foreseeably be perpetuated for generic bioequivalents.

148. Defendants' failures to address discrepancies in their manufacture, design, production and labels of batches/doses of Zantac during quality control testing, as well as their

[34] *See also* Peter Attia, The Drive, Episode #75: "David Light: Zantac recall due to cancer concerns – what you need to know," *available at* https://peterattiamd.com/davidlight/, at 1:00-1:03.

material misrepresentations, false statements, and other deceptive practices in continuing to claim that their Zantac product was safe for consumption and/or ingestion, have harmed Plaintiff and other Class Members.

149. Defendants had a duty to Plaintiff and other Class Members to ensure and warrant that their branded Zantac product (and in turn generic ranitidine based on Defendants' branded product) was manufactured, designed, and labeled appropriately; disclose any defect, contamination, impurity or other potential health hazard known or discoverable by Defendants; and to ensure that their Zantac product (and in turn generic ranitidine based on Defendants' branded product) was safe, reliable, and non-hazardous for human consumption—its intended purpose.

150. As alleged above, Defendants' own reckless acts and omissions resulted in cancer, or an increased risk of developing cancer for all members of the Class. Cancer is a serious disease-causing life-threatening illness and debilitating cellular, genetic, and physical injury. Technology, analytical tools, test and/or monitoring procedures exist and are readily available to provide for the testing and early detection of cancer in patients. These technologies, tools, tests and/or monitoring procedures are accepted and widely used by the scientific and medical community. These existing scientific methods include, but are not limited to cystoscopy, hematuria tests, and urine cytology.

151. Early detection of cancer in patients is one of the best, and sometimes the only means to treat cancer such that it does not cause lasting, permanent injury, illness, or death.

152. Early detection of cancer in patients necessarily allows patients to avail themselves of myriad forms of treatment, each of which is capable to altering the course of the

illness, such as bringing the cancer into remission, removal of any malignant tumors, and other treatment to alleviate injury.

153. The tests and treatments for the early detection and treatment of cancer must be prescribed by a qualified physician, and are conducted according to the latest, contemporary, and widely accepted scientific principles. Because NDMA-associated cancer screenings may not be conducted with the frequency necessary to identify cancer in the absence of exposure to NDMA, the prescribed monitoring regime is different from that normally recommended in the absence of exposure. Plaintiff and other Class Members require more frequent screenings not within the purview of routine medical exams.

154. The facts alleged above are sufficient or more than sufficient to plead a claim for medical monitoring as a cause of action.

155. Plaintiff seeks, on behalf of themselves and the Class Members whom they seek to represent, injunctive and monetary relief, including compensatory damages for, and the creation of a fund to adequately finance the costs of, medical monitoring procedures (1) to notify and alert all people exposed to NDMA contaminants as aforesaid of their exposure and the potential consequences, (2) to provide for necessary testing and screening including but not limited to blood tests, physical examinations, imaging, colonoscopies, endoscopies, and other similar methods for examination; biopsies, pathologic, histologic, and oncologic evaluations, oncologic, histologic, surgical and other necessary medical consultations, (3) to provide for necessary medical and surgical procedures for diagnosis and treatment, (4) to provide for all necessary evaluations and treatment, attorneys' fees, costs, interest, and such further relief as the Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for the following judgment:

A. An order certifying this action as a class action;

B. An order appointing Plaintiff as Class Representative, and appointing undersigned counsel as Class Counsel to represent the Class;

C. A declaration that Defendants are liable pursuant to each and every one of the above-enumerated causes of action;

D. An order awarding appropriate preliminary and/or final injunctive relief against the conduct of Defendants described herein;

E. Payment to Plaintiff and Class Members of all damages, exemplary or punitive damages, and/or restitution associated with the conduct for all causes of action in an amount to be proven at trial, including but not limited to the full amounts paid or reimbursed for generic bioequivalents of Defendants' branded Zantac products; the costs to replace or return those products because of recalls; and/or the increases in the amounts paid for non-adulterated, non-misbranded, generic bioequivalents in the wake of the recalls;

F. An award of attorneys' fees, expert witness fees, and costs, as provided by applicable law and/or as would be reasonable from any recovery of monies recovered for or benefits bestowed on the Class Members;

G. An award of statutory penalties to the extent available;

H. Interest, including but not limited to pre-judgment and post-judgment interest as provided by rule or statute; and

I. Such other and further relief as this Court may deem just, equitable, or proper.

DEMAND FOR JURY TRIAL

Plaintiff respectfully demands a trial by jury on all issues within the instant action so triable.

Dated: December 6, 2019

Respectfully submitted,

/s/ Stephen H. Galebach

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